MICHAEL P. WALLS
VICE PRESIDENT
REGULATORY & TECHNICAL AFFAIRS

March 6, 2017

Wendy Cleland-Hamnett (7401M)
Acting Assistant Administrator
Office of Chemical Safety and Pollution Prevention
William Jefferson Clinton Building
1200 Pennsylvania Avenue, N. W.
Washington, DC 20460

Re: Petitions to Order Testing of Tetrabromobisphenol A and the Chlorinated Phosphate Ester Cluster of Flame Retardants under Section 4(a) of the Toxic Substances Control Act

Dear Ms. Cleland-Hamnett:

On December 16, 2016, and January 6, 2017, the Environmental Protection Agency (EPA) received petitions made pursuant to section 21 of the Toxic Substances Control Act[1] (TSCA) requesting that EPA issue orders under TSCA section 4 to require testing by manufacturers and processors of Tetrabromobisphenol-A[2] (TBBPA) and the Chlorinated Phosphate Ester (CPE) cluster of flame retardants[3], respectively. The American Chemistry Council (ACC) strongly recommends that EPA deny the petitions in their entirety. ACC's comments below apply equally to both petitions.

ACC members companies would be subject to testing if the petitions are granted, and thus, have a direct interest in the Petitions.

The Petitions argue for a breathtakingly broad testing regime for manufacturers and processors of TBBPA and the CPE cluster. The testing would require the use of hundreds (if not thousands) of animals, and impose millions of dollars in testing costs. The Petitions are an attempt to force EPA to accelerate testing and assessment of the substances, well beyond that considered necessary by EPA. The Petitions interfere with EPA's mandate under recent amendments to TSCA[4] which require the Agency to designate priority substances, conduct risk evaluations on those substances,

[1] 15 U.S.C. § 2620 (2016).
[2] Petition of Earthjustice and the Natural Resources Defense Council to order testing of TBBPA under section 4 of the Toxic Substances Control Act (TSCA)(hereafter "TBBPA Petition"). Available at https://www.epa.gov/sites/production/files/2017-01/documents/tbbpa_petition_appendix_final.pdf.
[3] Petition of Earthjustice and the Natural Resources Defense Council to order testing of the Chlorinated Phosphate Ester Cluster under section 4 of TSCA (hereafter "CPE Petition"). Available at https://www.epa.gov/sites/production/files/2017-01/documents/cpe_test_petition_appx_final_0.pdf.
[4] Frank R. Lautenberg Chemical Safety for the 21st Century Act, P.L. 114-182, 130 Stat. 448 (June 22, 2016).

and manage unreasonable risks from those substances under the conditions of use. For the reasons set forth below, EPA should reject the petitions.

Section 21(b)(3) requires that EPA either agree to initiate actions requested in a petition or deny the petition within 90 days of receipt. Section 21 imposes on the petitioners the burden of proof to demonstrate that the information available to the Agency is insufficient to permit a reasoned evaluation of the risks to health and the environment, including a demonstration that the requested actions meet the applicable requirements.[5]

A. The Petitions Interfere with EPA's Mandate under Recent Amendments to TSCA

1. EPA Has the Discretion to Select Chemicals for Testing and Risk Evaluation

On June 22, 2016, then-President Obama signed into law the Frank R. Lautenberg Chemical Safety for the 21st Century Act. The law reflected the first major amendments to TSCA since its enactment in 1976.

The 2016 amendments require EPA, for the first time, to systematically review all existing chemicals in commerce. In order to accomplish that task, Congress required EPA to establish a process by which to identify priority substances for review, and a process to evaluate the risks of high priority chemicals.[6]

Despite establishing a one-year deadline for final rules governing the prioritization and risk evaluation processes, Congress recognized that EPA had already prioritized certain substances for review in its 2012 Work Plan Chemical Assessment Plan, which was updated in 2014.[7] The TSCA amendments required EPA to select 10 substances from the 2014 update of the Work Plan for risk evaluation, and to complete those risk evaluations within the deadlines established by the amendments.[8]

TBBPA and the CPE cluster were identified in the 2012 Work Plan as chemical substances for further assessment under TSCA.[9] Neither TBBPA nor CPE were included in the list of the first 10 substances for review by EPA.[10]

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[5] 15 U.S.C. § 2620(b)(4)(B).
[6] 15 U.S.C. § 2605(b). EPA has proposed rules to implement the prioritization and risk evaluation provisions of the Act. *See* Procedures for Prioritization of Chemicals for Risk Evaluation under the Toxic Substances Control Act, 82 Fed. Reg. 4825 (Jan. 17, 2017); Procedures for Chemical Risk Evaluation under the Amended Toxic Substances Control Act, 82 Fed. Reg. 7562 (Jan. 19, 2017).
[7] 15 U.S.C. § 2605(b)(2).
[8] *Id.*
[9] Office of Chemical Safety and Pollution Prevention, U.S. EPA, TSCA Work Plan Chemical Problem Formulation and Initial Assessment for Tetrabromobisphenol A and Related Chemicals Cluster Flame Retardants, Doc. No. 740-R1-4004 (2015) at 9 (hereafter EPA TBBPA Problem Formulation); Office of Chemical Safety and Pollution Prevention, U.S. EPA, TSCA Work Plan Chemical Problem Formulation and Initial Assessment for Chlorinated Phosphate Ester Cluster Flame Retardants, Doc. No. 740-R1-5001 (2015) at 7 (hereafter EPA CPE Problem Formulation).
[10] Designation of Ten Chemical Substances for Initial Risk Evaluations under the Toxic Substances Control Act, 81 Fed. Reg. 91927 (December 19, 2016).

The 2016 amendments grant EPA the discretion to determine what chemical substances will be designated as high priorities for assessment.[11] To ensure that EPA consistently has risk assessment work under way, the amendments require EPA to identify at least one new high priority for every risk assessment that is completed.[12] EPA's ability to designate additional priorities for assessment is limited only by the Agency's ability to complete risk evaluations in accordance with the deadlines established by Congress.[13] Thus, Congress requires EPA to carefully choreograph the identification of high priority substances and the evaluation of their risks, in order to ensure that appropriate resources are available to complete the evaluations within the established deadlines.

As aptly noted in EPA's recent denial of a TSCA section 21 petition on fluoride chemicals in drinking water:

> One of the key features of the new law is the requirement that EPA systematically prioritize and assess existing chemicals, and manage identified risks. Through a combination of new authorities, a risk-based safety standard, mandatory deadlines for action, and minimum throughput requirements, TSCA effectively creates a "pipeline" by which EPA will conduct review and management of existing chemicals. This new pipeline – from prioritization to risk evaluation to risk management (when warranted) – is intended to drive forward steady progress on the backlog of existing chemicals left largely unaddressed by the original law.[14]

It is evident that granting the petitions would upset EPA's mandate to "drive forward steady progress" on existing chemicals generally by forcing attention on chemical substances that EPA could have, but chose not to, assess in the first set of chemicals to be evaluated under the 2016 TSCA amendments. Under section 4(a)(2)(B)(ii), if EPA were to justify a test order on the basis that the requested studies are needed for prioritization, it would have to designate the chemicals as high-priority substances within 90 days of receiving the studies, thus triggering the deadlines for conducting risk evaluations. Otherwise, under section 4(f)(2), within 180 days of receiving the studies, EPA would have to initiate applicable action under section 6.

In effect, petitioners are requesting that EPA elevate the priority of TBBPA and CPE for risk evaluation. The effect of a successful section 21 petition is to disrupt EPA's established priorities so that EPA redirects its limited resources to the subject matter addressed by the petition, even if EPA does not consider that subject matter to be a priority. Section 21(b)(4)(B) recognizes that EPA's priorities are a relevant factor in its review of a petition.

As EPA has stated:

> Under this scheme [the 2016 amendments to TSCA], EPA does not believe that Congress

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[11] 15 U.S.C. § 2605(b)(2).
[12] 15 U.S.C. § 2605(b)(3)(C).
[13] *Id.* § (b)(2)(C).
[14] Fluoride Chemicals in Drinking Water; TSCA Section 21 Petition; Reasons for Agency Response, 82 Fed. Reg.11878, 11879 (Feb. 27, 2017) (hereafter Fluoride Petition Denial).

> intended to empower petitioners to promote chemicals of particular concern to them above other chemicals that may well present greater overall risk, and force completion of expedited risk evaluations and rulemakings on those chemicals, based on risks arising from individual uses.[15]

2. The Petitions Should Be Treated as Petitions for a Test Order Pursuant to Section 4(a)(2).

The Petitions are broadly styled as requests for EPA action under TSCA section 4(a). Petitioners make several citations to section 4(a)(1), which contains broad authority to mandate testing of chemical substances that was largely unchanged by the 2016 amendments.[16] It is clear from the language and anticipated outcome of the petitions, however, that petitioners are actually seeking an EPA test order under section 4(a)(2).

Section 4(a)(2) was added to TSCA section 4 to grant EPA the discretionary authority to issue a rule, order, or consent agreement to require the development of new information to review a notice under section 5, or to perform a risk evaluation under section 6, among other purposes.[17] Section 4(a)(3) further requires EPA to:

> [I]dentify the need for the new information, describe how information reasonably available to the Administrator was used to inform the decision to require new information, explain the basis for any decision that requires the use of vertebrate animals, and as, applicable, explain why issuance of an order is warranted instead of promulgating a rule or entering into a consent agreement.[18]

Even prior to the recent TSCA amendments, EPA had determined that a petition under section 21 must establish a regulatory need for the requested data.[19]

The Petitioners' requests for section 4 test orders must be denied for reasons similar to those found by EPA in denying the section 21 petition's request for a section 4 rule on polyvinyl chloride:

> EPA is denying the request for rulemaking under TSCA section 4 because the TSCA section 21 petition does not set forth sufficient facts for EPA to find that the toxicity information available to the Agency is insufficient to permit a reasoned evaluation of the health or environmental effects of these chemical substances, or for EPA to conclude that toxicity testing is necessary to develop any missing data.[20]

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[15] Fluoride Petition Denial at 11880.
[16] Even the section 4(a)(1) authority for issuing a test order requires a determination that testing is "necessary." See sections 4(a)(1)(A)(i)(III) and 4(a)(1)(B)(ii)(III).
[17] 15 U.S.C. § 2603(a)(2)(A)(i).
[18] *Id.* §2603(a)(3).
[19] 72 Fed. Reg. 72886, 72887 (Dec. 21, 2007) (denial of section 21 petition on air fresheners) (hereafter Air Freshener Petition Denial).
[20] Discarded Polyvinyl Chloride; TSCA Section 21 Petition; Reasons for Agency Response, 79 Fed.Reg. 64722, 64725. EPA went on to note that "[e]ven if the TSCA section 21 petition had established that the currently available toxicity information could be improved in particular respects for one or more of these chemical substances, it would

The Petitions fail to meet the standard established under section 4(a)(3) and section 21, which they must do.[21] Petitioners have failed to articulate how existing information informs the decision to request new testing; have failed to explain the basis for the extensive animal testing required by the petitions; and have failed to explain why a test order is warranted for TBBPA and the CPE cluster.

It is clear that Congress intended EPA to use its section 4 authority "judiciously, and only when needed to implement key provisions of the Act."[22] The Petitions fail completely in demonstrating that undertaking an extensive testing regime for TBBPA and the CPE cluster constitutes a "judicious" use of EPA authority in light of the mandate established by the 2016 TSCA amendments.

3. The Petitions Would Require Considerable Animal Testing

The 2016 TSCA amendments also imposed a significant new limitation on EPA testing requirements. For the first time, EPA is to take direct action to minimize the use of animals in testing.[23] Prior to making a request or adopting a requirement for testing using vertebrate animals, EPA must take into account available existing information and, when scientifically valid and justified, the availability of alternative non-animal means of generating the information.[24]

To date, EPA has conducted no analysis of measures to reduce the use of animal testing for TBBPA or the CPE cluster. Nevertheless, the petitioners have failed to include a comprehensive analysis of how existing information and potential alternative methods (e.g., computational toxicology) could reduce the use of animals in the requested tests that do require animals.

An unknown number of animals would be required to complete the testing should the Petitions be granted. In particular, ACC believes a large number of vertebrate animals – potentially thousands – would be required to conduct petitioners' requested testing of the toxicity of

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not automatically follow that the currently available toxicity information is insufficient to permit a reasoned evaluation of health or environmental effects." *Id.*

[21] *See, e.g.*, Fluoride Petition Denial at 11880 (where in the context of a petition for action under section 6(b), EPA noted that it "concludes that Congress intended for a petition to set forth facts that would enable EPA to complete a risk evaluation"). A similar conclusion is warranted for a petition for action under section 4.

[22] Report of the Senate Environment and Public Works Committee on the Frank R. Lautenberg Chemical Safety for the 21st Century Act, Rept. 114-67 at 10 (June 18, 2015) (hereafter EPW Report).

[23] 15 U.S.C. § 2603(h). The Senate Environment and Public Works Committee had this comment on the animal testing provisions:

> [The Act] includes extensive provisions by which EPA is to minimize the use of animals in testing under TSCA. EPA is to consider integrated testing strategies, greater efficiencies in testing through category approaches and formation of consortia, tiered testing and assessment strategies, and alternative testing methods, among others. Importantly, EPA is to develop a strategic plan to promote the development and implementation of reliable test methods to reduce, refine, or replace the use of laboratory animals. EPW Report at 10.

See also Congressional Record S3520 (June 7, 2016)(Statement of Senator Inhofe on section 4 during the Senate debate on LCSA).

[24] *Id.* § 2603(h)(1)(A) and (2)(C).

degradation products, reproductive, developmental and neurotoxicity testing, and testing for endocrine disrupting effects.

ACC believes that the compliance with both the spirit and the letter of the 2016 amendments requires EPA to articulate a non-animal testing strategy well in advance of granting petitions such as those put forward by the petitioners.

B. The Petitions Are Overbroad

Section 21(b)(4)(B)(i) of TSCA requires petitioners to demonstrate that information already available to EPA is not sufficient for a reasoned evaluation of the health and environmental effects of a chemical.[25] The section also requires petitioners to demonstrate that in the absence of such information, the chemical may pose an unreasonable risk or that the chemical is produced in substantial quantities and that it enters or may enter the environment in substantial quantities, or that there is or may be substantial or significant human exposure.[26] In addition, EPA has determined that the petitioner must establish that the requested testing is necessary to develop the data.[27]

The Petitions have not provided sufficient information for EPA to make these findings. The Petitions argue that there is known, readily available information that the substances pose a hazard of one form or another, allege that there are multiple exposure possibilities, and then conclude that data gaps identified by EPA under the TSCA Work Plan Chemical Program (EPA's Problem Formulation for TBBPA,[28] and for the CPE Cluster[29]) are an indication that EPA has "insufficient information to determine or predict the effects of the substances during their full life cycle."[30]

The Petitions offer little to support a finding that additional data is necessary. As detailed in the comments made by the North American Flame Retardant Alliance, there is a wealth of information already available on TBBPA.[31] ACC believes that sufficient information similarly exists for the CPE cluster.

While the Petitions certainly reflect data gaps that EPA has identified on the basis of prior problem formulation statements, there is no indication that the gaps must in fact be filled in order to support an EPA conclusion on the effects of those substances. The position of the petitioners is, in effect, that every data gap is a data need, and that therefore EPA should mandate a burdensome

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[25] 15 U.S.C. § 2620(b)(4)(B)(i)(I).
[26] *Id.* § 21(b)(4)(i)(II).
[27] Air Freshener Petition Denial at 72887 and 72892. *See also* 55 Fed. Reg. 17404, 17405 (Apr. 24, 1990) (new carpet emissions petition denial).
[28] TBBPA Problem Formulation at 11-12..
[29] CPE Problem Formulation at 12.
[30] TBBPA Petition at 11; CPE Petition at 11.
[31] Comments of the North American Flame Retardant Alliance (NAFRA), dated March 6, 2017; Comments of the NAFRA on EPA's TSCA Work Plan Chemical Problem Formulation and Initial Assessment, dated November 18, 2015 (Docket ID EPA-HQ-OPPT-2015-0068).

and expensive testing regime as a consequence. This position is contrary to the letter and the spirit of the 2016 amendments to TSCA. As EPA has long recognized, few chemicals have a complete data set; nearly all have data gaps. In revising TSCA, Congress expressly rejected the idea that section 4 should be used "for the purposes of establishing or implementing a minimum information requirement of broader applicability," i.e., that data gaps should be filled solely because they exist and not because EPA has a regulatory need to fill them.

Granting the Petitions is inapposite where, as here, EPA has already indicated that it intends to conduct an analysis of the risks associated with only particular exposures.

EPA's 2015 TBBPA Problem Formulation indicated that the Agency would assess the risks of certain specific environmental and human health exposures, particularly risks to organisms near two identified manufacturing facilities, workers at manufacturing and processing facilities who may inhale the substance, and aggregate oral exposure from limited oral exposure pathways, including indoor or outdoor sources, or from the consumption of fish.[32] Notably, EPA indicated that it would not assess the risks to the general population near processing sites, from product disposal or recycling, or drinking water, among others.[33]

In the case of the CPE cluster, EPA concluded in its 2015 problem formulation that it would assess the potential environment risks to aquatic organisms, and would evaluate the health risks from inhalation, ingestion or consumption of CPEs in drinking water, as well as from aggregate oral exposures.[34] Notably, EPA determined that it would not assess risks from releases from manufacturing or processing, including the manufacture, formulation or use of CPEs in certain products.[35]

The Petitions seek testing on an expansive set of endpoints – 17 different tests for various endpoints – far beyond those that might support the EPA assessments it has decided to conduct. For example, in the TBBPA problem formulation, EPA has concluded that it will not assess the risks from dermal exposure, drinking water, or disposal.[36] Yet the TBBPA Petition includes proposed testing requirements for dermal exposure, drinking water, and disposal.[37]

These tests come at a high cost in terms of animal usage and expense. ACC estimates that the battery of tests required by the Petitions would cost well in excess of $1.1 million, and certainly multiples times that amount depending on the breadth of the testing regime (e.g., the number of mixtures potentially subject to testing). More importantly, granting the Petition would upset the regulatory framework established by Congress in the 2016 amendments to TSCA, and would be contrary to the decision made by EPA to focus its risk evaluation attention on other substances.

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[32] EPA TBBPA Problem Formulation at 9.
[33] *Id.* at 10.
[34] EPA CPE Problem Formulation at 7.
[35] *Id.*
[36] EPA TBBPA Problem Formulation at 10.
[37] TBBPA Petition, Appendix A, at 1, 5, 12, respectively.

C. The Petitions Would Require Testing for Thousands of Mixtures

The Petitions note that the subject flame retardants are widely used as additives in a significant number of products, including paints and coatings, textiles, and insulation and foam. As such, the Petitions would have the effect of requiring manufacturers and processors to test a substantial number of mixtures.

TSCA section 4(a)(1)(B) requires EPA to make a specific finding in the case of testing on mixtures. EPA must find that the effects of the mixture on health or the environment "may not be reasonably and more efficiently determined or predicted by testing the chemical substances which comprise the mixture."[38]

In this case, testing of hundreds or thousands of mixtures is simply unnecessary.

Citing section 4(a)(2), EPA has denied petitions for the testing of mixtures in similar situations, and it should do so here as well.[39] EPA's denial of the Petitions on this basis would be well within EPA's discretion.

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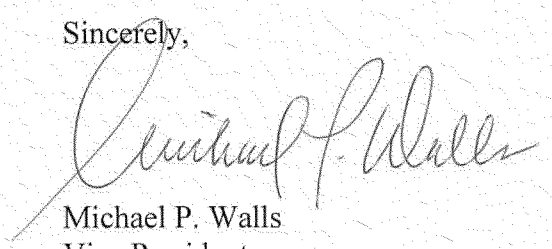
In conclusion, EPA should deny the Petitions in all respects. If you have any questions regarding ACC's comments on the Petitions, please contact me at mike_walls@americanchemistry.com, or 202-249-6400.

Sincerely,



Michael P. Walls
Vice President
Regulatory & Technical Affairs

cc: Administrator Scott Pruitt

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[38] 15 U.S.C. § 2603(a)(1)(B). The legislative history of TSCA explains the rationale: "The assessment of safety of a mixture may well be based upon the toxicity of particular components, and tests of the entire mixture with its varying component ratios may be unnecessary or unrewarding." *See* H.R. Rep. 94-1341 (1976) at 18, Legislative History of the Toxic Substances Control Act (1976) at 425.

[39] EPA made this point in connection Air Freshener Petition Denial, 72 Fed. Reg. at 72887. EPA further made the point that section 21(b)(4)(B)(i) does not provide for judicial review of a denial of a petition for a test rule on mixtures, concluding that "Congress left the complex issues associated with the testing of mixtures to the Administrator's discretion." *Id.*